REMARKS

Applicants respectfully request reconsideration of this application in view of the above amendments and the following remarks.

Claims 1-17 are pending. Claims 1, 6, 8, 10, 12, and 14 are independent and have been amended, as further discussed below.

Claims 1-3 recite a composition comprising: a) a laxative selected from the group consisting of bisacodyl and enteric coated vanilloid compounds; and b) simethicone in an amount of about 10 mg to about 500 mg per dose. Claims 6-13 recite methods of treating various conditions by administering an effective amount of this composition to a human. Claims 14-17 recite a method for enhancing the efficacy of a laxative selected from bisacodyl and enteric coated vanilloid compounds by administering to a human therewith an effective amount of simethicone.

Claims 1-17 have been rejected under 35 U.S.C. §112, first paragraph, as not enabled by the specification. The Examiner argues the specification does not reasonably provide enablement for vanilloid compounds, including capsaicin. The Examiner cites Vazquez-Olivenicia et al. and Yerra et al. to show that vanilloid compounds have different effects on gastric motility, and one skilled in the art would therefore have to perform undue experimentation to determine which vanilloid compounds in what amounts would be effective as laxatives.

Applicants disagree. The specification provides ample enablement for vanilloid compounds. Page 2, line 30 through page 3, line 21 gives a detailed description of the laxative compounds, bisacodyl and enteric coated vanilloid compounds, useful in the invention. Appropriate amounts of vanilloid compounds are given on page 3, lines 3-4. The first and second full paragraphs of page 3 give further details and examples of vanilloid compounds. Applicants submit this rejection is without merit.

Claims 1-17 stand rejected under 35 U.S.C. §112, second paragraph, as indefinite. The Examiner argues that the claims omit an effective amount of bisacodyl or enteric coated vanilloid compound. The Examiner argues that vanilloid compounds can be used as flavorings, and therefore the amount required to act as a laxative should be specified in the claims.

Applicants again disagree. Useful amounts of both laxatives are given in the specification. However, the claims need not contain numerical ranges, which would in fact be apparent to a worker in this field.

The Examiner also argues claims 14, 16, and 17 were missing the step of administration to a human. Claim 14, the independent claim among these, has been amended to recite --administering to a human-- in the last line.

Claims 1, 3, 5, 6, 8, 10, 12, 14, and 15 stand rejected under 35 U.S.C. §102(b) as anticipated by, or in the alternative under 35 U.S.C. §103(a) as obvious over, Drug Launches (1993) Abstract. The Examiner argues Drug Launches discloses a composition containing bisacodyl and simethicone and methods of treating various conditions.

Claims 1, 3-6, 8, 10, 12, and 14-16 have been rejected under Section 103(a) as obvious over Drug Launches (1993) in view of the acknowledged prior art (specification, page 1, lines 27-31, referencing US 5,418,220 disclosing simethicone used to the treatment of constipation), Schmidt et al. (US 5,424,064), Holtman et al. and Sable et al. The Examiner acknowledges that the difference between the prior art and the claimed invention is that the references do not expressly disclose a composition or method for enhancing the effect of a laxative by providing therewith simethicone in an amount of about 10 mg to about 500 mg per dose (recited in claim 4). The Examiner argues, however, that the prior art suggests the same, as it is known that simethicone is suitable for increasing intestinal motility.

Applicants have amended all the independent claims herein to recite that simethicone is present in an amount of about 10 mg to about 500 mg per dose. No new matter is added by this amendment, the subject matter of which is found in original claim 4, now canceled. None of the cited references teaches or suggests use of this amount of simethicone in combination with a laxative to enhance the efficacy of the laxative. Moreover, applicants disagree that it is known that simethicone is suitable for increasing intestinal motility. The Examiner gives no evidence for this statement. In addition, according to applicants' data in Example 1, the use of simethicone alone had no effect on small bowel transit in rats treated therewith. Accordingly, the Examiner assertion that simethicone is known to increase intestinal motility appears to be without merit.

For these reasons, applicants submit that the claims as amended are patentable. Early and favorable reconsideration is requested.

Attached hereto is a marked-up version of the changes made to claims by the current amendment.

Respectfully submitted,

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